

Appln. No. 09/716,356
Amd. dated March 2, 2005
Reply to Office Action of September 9, 2004

Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

1(Original). A purified polypeptide, comprising an amino acid sequence selected from the group consisting of:

(a) SEQ ID NO:6; where amino acid residue 73, as represented by Xaa, is Ile or Thr;

(b) a contiguous fragment of SEQ ID NO:6, which fragment induces interferon- γ production in immunocompetent human cells; and

(c) a variant of (a) or (b) differing therefrom by replacement of one amino acid residue, which variant induces interferon- γ production in immunocompetent human cells.

2(Original). The purified polypeptide of claim 1, which has a molecular weight of about $18,500 \pm 3,000$ daltons on sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE) and an isoelectric point of about 4.9 ± 1.0 on chromatofocusing.

Claim 3 (Cancelled)

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4(Original). The purified polypeptide of claim 1, which comprises the amino acid sequence of a contiguous fragment of SEQ ID NO:6, where amino acid residue 73, as represented by Xaa, is Ile or Thr, which fragment induces interferon- γ production in immunocompetent human cells.

5(Original). The purified polypeptide of claim 1, which comprises a variant of (a) or (b) differing therefrom by replacement of one amino acid residue, which variant induces interferon- γ production in immunocompetent cells.

6(Original). A pharmaceutical composition, comprising the polypeptide of claim 1 as an active ingredient and a pharmaceutically-acceptable carrier.

7(Original). The pharmaceutical composition of claim 6, further comprising interleukin 2.

8(Original). The pharmaceutical composition of claim 6, further comprising interleukin 12.

9(Original). The pharmaceutical composition of claim 6, further comprising interleukin 3.

Claims 10-17 (Cancelled)

18(Currently amended). A pharmaceutical composition,

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comprising:

(i) an interferon- γ inducing polypeptide selected from the group consisting of (a) a polypeptide of SEQ ID NO:6 obtainable from humans, where amino acid residue 73 of SEQ ID NO:6, as represented by Xaa, is Ile or Thr, (b) a contiguous fragment thereof, or (c) a homologous polypeptide thereof, wherein the polypeptide of SEQ ID NO:6 and the homologous polypeptide thereof have the following physicochemical properties:

- (1) an amino acid sequence selected from the group consisting of SEQ ID NO:6, where amino acid residue 73, as represented by Xaa, is Ile or Thr, and a homologous sequence thereof where at least one amino acid residue in SEQ ID NO:6 is replaced with a different amino acid, or at least one amino acid residue is added to or deleted from the N-terminus and/or the C-terminus of SEQ ID NO:6, wherein said homologous polypeptide has substantially the same physicochemical properties and biological activity as the polypeptide of SEQ ID NO:6,
- (2) molecular weight
18,500 \pm 3,000 daltons on sodium dodecyl sulfate

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polyacrylamide gel electrophoresis (SDS-PAGE);

(3) isoelectric point (pI)

4.9 ± 1.0 on chromatofocusing;

(4) biological activity

inducing interferon- γ production by human

immunocompetent cells;

(5) acute toxicity

having an LD₅₀ of at least about one mg/kg when

tested in mice; and

(6) assay

being detected with a monoclonal antibody ~~specific~~

~~to the said polypeptide or said homologous~~

~~polypeptide; and~~ which binds to the interferon- γ

inducing polypeptide having an amino acid sequence

of SEQ ID NO:6;

(ii) a pharmaceutically acceptable carrier; and

(iii) may optionally comprise one or more compounds selected from

the group consisting of an adjuvant, excipient, diluent,

stabilizer, and a second biologically active compound, said

pharmaceutical composition being administered to a subject—

~~adjuvant, excipient, diluent, and/or stabilizer, said~~

~~pharmaceutical composition being administered to a subject after~~

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~~being processed in combination with or without a biologically
active compound.~~

19(Currently amended). A pharmaceutical composition,
comprising (i) an interferon- γ inducing polypeptide having the
amino acid sequence of SEQ ID NO:6, where amino acid residue 73,
as represented by Xaa, is Ile or Thr, or a fragment thereof, and
having the following physicochemical properties:

(1) molecular weight

18,500 \pm 3,000 daltons on sodium dodecyl sulfate
polyacrylamide gel electrophoresis (SDS-PAGE);

(2) isoelectric point (pI)

4.9 \pm 1.0 on chromatofocusing;

(3) biological activity

inducing interferon- γ production by human
immunocompetent cells;

(4) acute toxicity

having an LD₅₀ of at least about one mg/kg when
tested in mice; and

(5) assay

being detected with a monoclonal antibody ~~specific~~
~~to the said polypeptide or said homologous~~
~~polypeptide; and~~ which binds to the interferon- γ

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inducing polypeptide having an amino acid sequence
of SEQ ID NO:6;

(ii) a pharmaceutically acceptable carrier; and

(iii) may optionally comprise one or more compounds selected from
the group consisting of an adjuvant excipient, diluent,
stabilizer, and a second biologically active compound,~~adjuvant,~~
~~excipient, diluent, and/or stabilizer, said pharmaceutical~~
~~composition being administered to a subject after being processed~~
~~in combination with or without a biologically active compound.~~

20(Original). The pharmaceutical composition of claim 18, wherein said interferon- γ inducing polypeptide is said homologous polypeptide.

21(Previously presented). The pharmaceutical composition of claim 18, which is used as an antitumor agent, antiviral agent, antiseptic, immunotherapeutic agent, platelet-increasing agent, or leukocyte-increasing agent.

22(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is interferon- α .

23(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is interferon- β .

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24(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is interleukin 2.

25(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is interleukin 3.

26(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is interleukin 12.

27(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is TNF- α .

28(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is TNF- β .

29(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is carboquone.

30(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is cyclophosphamide.

31(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is aclarubicin.

32(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is thiotepa.

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33(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is busulfan.

34(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is ancitabine.

35(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is cytarabine.

36(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is 5-fluorouracil.

37(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is 5-fluoro-1-(tetrahydro-2-furyl) uracil.

38(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is methotrexate.

39(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is actinomycin D.

40(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is chromomycin A3.

41(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is daunorubicin.

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42(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is doxorubicin.

43(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is bleomycin.

44(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is mitomycin C.

45(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is vincristine.

46(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is vinblastine.

47(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is L-asparaginase.

48(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is radio gold colloidal.

49(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is Krestin®.

50(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is picibanil.

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51(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is lentinan.

52(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is Maruyama vaccine.

Claims 53-94 (Cancelled)